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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,436	02/14/2001	Corine A. M. Vernet	15966-672	1641

7590 03/30/2004

INTELLECTUAL PROPERTY  
CURAGEN CORPORATION  
555 LONG WHARF DRIVE 9TH FLOOR  
NEW HAVEN, CT 06511

EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/783,436	Applicant(s) VERNET ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 29, 32 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 29, 32 and 52-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>dictionary</u> .                       |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a Final rejection (mailed on July 10, 2003), Applicants filed a request for continued examination and an amendment received on January 12, 2004. Said amendment cancelled Claims 49-51 and amended Claim 55. Thus, Claims 1, 29, 32, and 52-57 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/182,637 filed on February 15, 2000, 60/237,862 filed on October 4, 2000, and 60/240,316 filed on October 13, 2000.

### ***Withdrawn – Objections to the Specification***

3. Previous objection to the amendment filed April 24, 2003 to the sequence listing under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn. Applicants argue the encoding nature of SEQ ID NO:5; the Examiner was unable to confirm this due to the unavailability of an alignment of SEQ ID NOs: 5 and 6 from pages 10-12 of the specification.. However, on page 10, line 25, SEQ ID NO:6 is described as containing 617 amino acid residues. Moreover, in the disclosure of SEQ ID NO:6 in Table 6, it is clear from the numbering the “---“ is intended as an unknown residue and not a gap as is commonly used in the art. Thus, the Examiner agrees that there is support for the amendment, and the objection is herein withdrawn.

***Maintained – Objections to the Specification***

4. Previous objection to the Tables where they contain different SEQ ID NOs identifying identically labeled sequences is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons (Table 7 on pages 12-13 will be considered as an example). CHR Y is noted as 78289-78452 followed by the identifier SEQ ID NO:19; this is unclear because SEQ ID NO:19 is only 164 nucleotides long, thus rendering the numbering in Table 7 confusing. The Examiner maintains that, to be clear, the table should recite ---CHR Y fragment--- or similar language. The Examiner disagrees that this nomenclature is used in the art; no prior art support for this statement has been set forth.

The confusion at issue is found in the following Tables:

- a) Tables 7 and 8 both recite CHR Y nucleic acid sequences, but with different SEQ ID NOs to reference them.
- b) Tables 9, 11, and 25 all recite GLY T polypeptide sequences, but with different SEQ ID NOs to reference them.
- c) Table 15 recites two different PP1201 nucleic acid sequences, but with different SEQ ID NOs to reference them.
- d) Tables 16 and 20 both recite CHR 2 nucleic acid sequences, but with different SEQ ID NOs to reference them.

Appropriate correction is required.

5. Previous objection to Table 18 on page 24 is maintained for the reasons noted above. As previously noted, "NOV5 polypeptide is labeled as SEQ ID NO:38 in Table 18 while the text describes NOV5 polypeptide sequence as SEQ ID NO:10. Which description is correct?"

Clarification is required.

6. Previous objection to the specification for having inappropriate Tables 2-27 imbedded in the text is maintained. Applicants argue that the M.P.E.P. § has no requirement that the data in Tables 2-27 be presented in another format' the Examiner disagrees.

“The specification, including the claims, may contain chemical and mathematical formulas, but shall not contain drawings or flow diagrams. The description portion of the specification may contain tables” see 37 C.F.R. § 1.58

While the specification describes these depictions as “Tables”, they do not conform to the definition of a table. In Stedman’s Medical Dictionary 27<sup>th</sup> Edition found on-line, a definition of a “table” is “2. An arrangement of data in parallel columns, showing the essential facts in a readily appreciable form” (see attachment). No parallel columns are used to present the data in these depictions. Absent another appropriate description, the Examiner finds that these are drawings (not tables), which must be presented in the Formal Drawings and described in the Brief Description of the Drawings for clarity. Correction is required.

7. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. Applicants argue that the newly substituted Abstract meets the requirements; the Examiner disagrees. The Abstract, as amended by Applicants on January 12, 2004, lacks a clear description of the molecules described in that the abbreviation “NOVX” is wholly unclear. Moreover, the source of all NOVX molecules, and not just the preferred embodiment, must be noted for clarity. As noted in M.P.E.P. § 608.01(b), the Abstract must describe the disclosed subject matter in its entirety, not just the claims. Correction is required.

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***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claims 49-51 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's cancellation of said claims.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

9. Previous rejection of Claims 55-57 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the amendment to add the functional limitation to the claims obviates the rejection; the Examiner disagrees. SEQ ID NO:14 is a 695 amino acid protein suggested to be an acetylglucosaminyl transferase polypeptide. While this portion of the protein (158-338) aligns with conserved regions in glycosyltransferases, nowhere in the specification is it asserted to garner the required activity for the claim. This required structural piece is about 25% of the full-length protein. With such a small portion of the protein being required, the ability to correlate structure and function is extremely low. Thus, the structure, not being indicative of the limiting function, cannot impart the necessary structure required for adequate written description of the instant claims.

**NEW ISSUES**

***Claim Rejections - 35 U.S.C. § 101***

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1, 29, 32, and 52-57 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. The NOV7 polypeptide (SEQ ID NO:14) is described as

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having similarity to a human acetylglucosylaminyltransferase-like protein and as containing a conserved glycosyltransferase region (see page 31 of specification); no positive assertion that NOV7 is an acetylglucosylaminyl transferase is found in the specification.

If a positive assertion that SEQ ID NO:14 is an acetylglucosylaminyltransferase is found in the specification, utility for such a protein might be argued using the description. However, no specific applications of acetylglucosylaminyl transferases are described. On page 32, uses for the protein in protein therapeutics, small molecule targeting, etc. are postulated, but without a link between SEQ ID NO:14 and a reason to affect the protein in a human, these postulates cannot be considered specific utilities. Various diseases and disorders (see pages 32-33) are suggested, again, none with a direct link to SEQ ID NO:14. On page 36, NOV7 is described as being useful in diagnosing and measuring carcinogenic and metastatic onset and progression; however, no specific link to support a specific utility is set forth; moreover, a protein's role in such diagnosis is unclear and use of SEQ ID NO:14, most directly, is unfounded. For all these reasons, the claimed invention lacks utility.

#### ***Other Art of Interest***

11. Previously cited WO 02/26950 (Lal *et al.*) discloses SEQ ID NO:14 that is 93% identical to Applicants' SEQ ID NO:14 (see attached alignment). The sequence of Lal *et al.* contains the 158-338 fragment in Claim 55.

#### ***Summary of Pending Issues***

12. The following is a summary of the issues pending in the instant application:

a) The specification stands objected to for having unclear labeling of sequences.

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- b) The specification stands objected to for having inappropriate Tables imbedded in the text.
- c) The Abstract stands objected to for not completely describing the disclosed subject matter.
- d) Claims 55-57 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- e) Claims 1, 29, 32, and 52-57 stand rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

***Examiner's Comments on Prior Art***

13. The closest prior art to SEQ ID NO:14 and particular fragments thereof was previously noted as GenBank Accession Number AW177837 teaches a 675 bp mRNA whose sequence exactly encodes SEQ ID NO: 14 residues 176-400 (of the full-length 695 sequence). GenBank Accession Number AW177837 does not teach the encoded protein of the EST. Nor does GenBank Accession Number AW177837 teach methods of identifying a full-length gene and producing its protein product.

***Conclusion***

14. No claims are allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

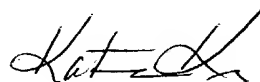
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Examiner  
Art Unit 1652

March 25, 2004